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Indicators of Future Ulceration in Diabetes Patients of Low-Moderate Foot Risk

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Abstract

Background & Aim: Diabetes Mellitus can cause serious health problems including foot complications. Peripheral neuropathy affects the outer appendages, most commonly the lower limbs. Ulceration of the feet has a high possibility of advancement to amputation; thus greatly diminishing quality of life. This study investigates if patients with diabetes, who are at low-moderate risk of foot disease, have any underlying biomechanical signs which may indicate that they are at risk of future ulceration.

Methods: Twenty patients with Diabetes Mellitus at low-moderate risk of foot disease and 32 healthy individuals participated in this study. All participants completed a self-administrated questionnaire (assessing socio-demographic and lifestyle factors) and underwent a clinical foot screening examination (plantar sensation, pedal pulses and ankle range of motion), gait assessment (spatio-temporal parameters) and barefoot plantar pressure analysis. Results between the 2 groups were compared.

Results: Major differences were observed in area of plantar pressure distribution, walking speed and foot alignment between low-moderate risk participants with diabetes and healthy controls. Low-moderate risk participants with diabetes recorded elevated dynamic plantar pressure in regions of metatarsal heads and the heel. Plantar pressure was correlated with arch type and foot alignment (p<0.05). Dissimilarities were not observed for lifestyle behavior and ankle range of motion.

Conclusion: This pilot study demonstrated a group of patients with diabetes at low-moderate risk of foot disease showing significant differences in biomechanical measures that are linked to callus/ulcer formation. Risk factors for ulceration previously reported for high risk patients with diabetes also affect patients with low-moderate foot risk.

Keywords: Low-moderate risk diabetic foot; Plantar pressure; Foot screening; Temporal parameters

Introduction

Lower limb complications as a direct consequence of Diabetes Mellitus (DM) is a growing concern globally [1]. Foot ulceration pertaining to DM (DFU) is a prevalent complication [2,3]. It is suggested that 15% of people with DM will attain a DFU in a lifetime and even more shocking is that 2.5% of patients with DM will experience DFU annually [4]. The epidemiologies of DFU and subsequent effects have been widely reported [5-7]. Numerous determinants of ulceration exist, but often it is a presence of more than one determinant that will lead to ulcer development. Payne et al. [8] conducted a study in relation to the determinants of elevated plantar pressure. The main causation factors discussed are increased body weight, neuropathy, foot structure/deformity, limited joint mobility, muscle strength and changes to plantar soft tissue. Increasing research has also being carried out in the area of DFU prevention [7,9-13]. The majority of this preventative research is performed with respect to patients that have experienced previous ulceration where, it is obvious that the risk of future ulcer development is increased. Identifying those patients that are at risk at an earlier stage, prior to lower limb

complications, would be a major advancement in this area to promote prevention.

The spatio-temporal parameters examined in this study are descriptive of the biomechanical characteristics of walking [14]. Irregularities within these features can be the first warnings of discrepancies in lower limb gait. Also spatial and temporal parameters are a major indication of the degree of functionality [15]. In previous studies comparisons have been made between DM patients with peripheral neuropathy, DM patients without neuropathy and healthy controls. Results have been inconsistent; Sacco et al. [16] demonstrated increased double and single support times in subjects with peripheral neuropathy, while DM patients without neuropathy and controls showed similar findings with no significant differences in gait parameters. This study implies negligible changes in the non-neuropathic group. Katoulis et al. [17] and Mueller et al. [18] reported no significant difference in gait parameters between DM cohort and controls.

Plantar pressure profiling when coupled with gait parameter analysis is a particularly reliable method of assessing lower limb function. A substantial number of authors have investigated the plantar pressure values of DM and neuropathic patients with the notion of high pressure areas to be linked to ulcer sites. Many studies

concluded that the presence of neuropathy was responsible for a major increase in plantar pressure across all findings [8, 19,20]. Armstrong et al. [21] and Ctercteko et al. [22] along with others [23-25] have concluded that the hallux, heel and mid-metatarsal regions are those most inclined to develop calluses and ulceration. Van Schie et al. [26] investigated the effect of arch index and body mass on plantar pressure for DM subjects and did not detect any difference in peak plantar pressure between the healthy and pathological groups.

We intend to eliminate the effects of body weight by comparing against case matched controls. By recruiting low- moderate risk patients, the existence of neuropathy and changes to plantar soft tissue will not be an issue. Removal of these high risk factors will allow less influential triggers of foot disease to be brought to the fore such as baseline pressure, walking biomechanics, foot characteristics and behavioral attributes. Connecting aspects of participant's daily régime, by means of questionnaire, with foot biomechanical characteristics may yield results which will indicate if certain lifestyle choices are a help or a hindrance on development of foot disease.

The primary objective of this study is to investigate if factors correlating with the determinants of ulceration are present in DM patients prior to diagnosis of diabetic foot disease. Comparing the low-moderate foot disease risk patients to non-DM controls allows for a baseline comparison in all areas examined.

Research Design and Methods

Participants

This is an exploratory case comparison study involving 20 patients with (type 1 and type 2) DM at low-moderate risk of diabetic foot disease and 32 healthy volunteers.

The DM cohort was recruited through two General Practice centers, where specific diabetes clinics take place. Volunteers with DM were invited to attend their respective health center to undergo a foot screening examination which determined their level of risk to foot disease based on The Diabetic Foot Risk Stratification and Triage Guidelines (SIGNS) [27]. The SIGN system classifies foot disease risk in four categories from low to active. Classification of low-moderate diabetes foot risk implies patients present with less than one foot risk factor. Risk factors specifically pertain to loss of sensation or indications of peripheral vascular disease but without the advancement to callus formation or deformity. Patients that fell within the low to moderate risk group were invited to participate in further clinical and gait assessments.

Healthy volunteers in the control group were recruited among students and staff of a third level educational institution, the Cork Institute of Technology, Ireland, and the local community, who responded to an advertisement distributed by email, and/or word of mouth. Participants in the control group were matched to patients with diabetes according to gender, weight and height.

The inclusion criteria for the study were within the age profile of 20 to 70 years, in good general health as assessed by their GP, no history of previous lower limb surgery or ulceration, no neurological or orthopaedic impairments such as severe knee deformations (genu valgum/genu varum) or severe foot deformities that would adversely affect their gait.

All participants in the study received verbal and written information about the nature of project and signed informed consent prior to taking part in this research. Ethical approval for this study was attained from the ethical review committee of Cork Institute of Technology.

Questionnaire

A study specific questionnaire was compiled based on (i) WHO STEPSwise approach for chronic disease and risk factor surveillance-Instrument 2.1 [28], (ii) ACP Clinical Skills Module "Diabetic Foot Ulcers" [29] and (iii) Behavioural Risk Factor Surveillance System Questionnaire [30]. The participants were asked to complete this self-administered questionnaire in order to collect information on their socio-demographic situation, overall physical health including blood pressure history and foot care routine, diet, tobacco use, alcohol consumption and level of physical activity.

Clinical examination

All participants underwent a comprehensive clinical foot examination which was carried out in accordance with NICE guidelines [31]. Lower limb assessment analysed foot disease risk factors in areas of plantar sensation, pedal pulses and also a visual exam was conducted. In relation to plantar sensation, greater than two absent plantar sites was criteria for exclusion in accordance with SIGNS. More than one absent pulse was also exclusion criteria for the same reasoning. Deformity, hard skin, discoloration, hair growth, callus formation and any signs of shoe-wear were noted via visual exam. In addition, ankle range of motion, sub-talar joint alignment, medial longitudinal arch type and self-assessed foot history were recorded.

Gait assessment

Lower body gait analysis was carried out using 3D Vicon motion analysis system (VICON Ltd, UK). Retro-reflective markers were attached to the lower body according to the Oxford Foot Model recommendations. All participants were asked to walk at self-selected speed along a 17 m path with the middle 12 m being designated for data collection. On average fifteen trials were recorded and five were selected for further analysis. Spatio-temporal parameters including cadence, Step/Stride length, single/double support and walking speed are presented and discussed for the purpose of this research. The gait cycle is the time internal between two successive occurrences of one of the repetitive events of walking for example heel strike to heel strike. The parameters then describe events and phases within a gait cycle. Step length describes the distance one foot moves in front of the other during a gait cycle, while step time is the time taken to complete one step. Stride length is the distance to carry out a stride and stride time, the time to complete one stride. The period during the gait cycle in which both feet are in contact with the ground is referred to as double support while single support describes the period when only one foot is contact with the ground. Cadence is the number of steps recorded in a specified time. Walking speed, the distance travelled per minute.

Plantar pressure examination

Tekscan HR Mattm pressure mapping system (Tekscan, Inc., US), with sensor spatial resolution of 4 sensels/cm2 and recording at 80 Hz was used to capture barefoot plantar pressure distribution and analyse foot function. Equipment was calibrated to each subject's body mass prior to assessment. The peak pressure was analysed under hallux, head of 2nd and 3rd metatarsal (M2M3) and the heel as these areas are

more susceptible to formation of calluses and pressure ulcers. Only footprints which occurred after initiation of walking (second or third step) were utilised for profiling. Also trials were eliminated if the subject did not strike the mat correctly or if the subject seemed to adapt their gait to aim for the mat.

Statistical analysis

Statistical analysis was performed using the OriginPro 8.1 (OriginLabCorporation, US). Data distribution was assessed with Shapiro-Wilk and histogram tests. Normally distributed continuous variables were subjected to two tailed t-tests. Mann-Whitney test was used on skewed data. Pearson Chi-squared test was performed on categorical data. A p-value of less than 0.05 was considered statistically significant.

Results

Socio-demographic and behavioral attributes

Characteristics shown in Table 1 denoted participants' demographics. The DM group displayed a higher body mass index (BMI) although not significantly different. Both groups are in the BMI classification of overweight. DM subjects were older (18 men, 2 women, mean age: 54. 5 years) compared to control group (26 men, 6 women, mean age: 35 years). In relation to lifestyle, 50% of DM patients were in employment compared to 87. 5% (p>0.05). A higher proportion of the DM group are current smokers. Both populations were comparable under topic of diet (p>0.05). Major differences were described concerning exercise, specifically the amount of exercise used as transport (walking/cycling). The controls were significantly lower. The volume of participants that had been told they had hypertension was expectantly higher for the DM group (p<0. 05).

Pertaining to foot care routine (Table 2), only 60% of participants responded that they had been informed of correct foot care practice. Also, 15% reported that their feet had never been examined by a health professional. Orthotics had previously been prescribed to 25% of DM group but minority follows the guidelines for use.

Clinical characteristics

Foot Physiognomies: Sensory exam and vascular function assessment both yielded similar results (p>0.05) in accordance with categorical risk of subjects enrolled. A higher occurrence of flat arch type emerged from the DM group (Table 3). This characteristic was a majority with this DM group (52. 36%). In accordance with the criteria of the study DM participants indicated towards pronated foot alignment (42%).

Temporal Parameters: The comparison of gait characteristics between the DM and control groups is presented in Table 4. Significant differences between the 2 groups were detected for three variables, double support, foot-off, walking speed (p<0.05). Cadence and step length were recorded as similar between groups; however DM group exhibited a slower walking speed of 1.1 ± 0.12 m/s compared to 1.2 ± 0.5 m/s (P=0.04). The instance of Foot off within the gait cycle was later in the DM group (p<0.05). This refers to specific time the foot lift off the ground during the gait cycle. In accordance with this fact the time spent in double support phase of stance was also increased for DM group (p<0.05).

Plantar Pressure Analysis: Dynamic peak pressures during ambulation are conveyed in Table 5. The highest plantar pressures were recorded at the hallux, metatarsal heads (M2M3) and heel. Comparing results between groups, the hallux reported similar mean values (p>0.05). Highest plantar pressure was recorded in the metatarsal head region across the board, with the DM and controls experiencing 620.3 ± 166.6 KPa and 479.9 ± 187.0 KPa respectively (p=0.012). The heel reported peak pressure values of 457.5 ± 147.0 KPa for case cohort and 363.2 ± 104.0 KPa for control group (p=0.011).

Discussion

The present study compares cross-sectional data of a group of low-moderate diabetes foot risk patients to controls. The chief aim of this study was to investigate if DM has consequences on the lower limbs, which, with early or non-existent foot complications, are undetectable with basic clinical foot assessments. It was anticipated by the authors that biomechanical differences would emerge that would indicate that low-moderate risk patients require more vigilant care.

Analysis of results yielded an apparent observation; limited significant differences emerged across the board (Tables 1-5). This may be due to selection bias. Participants were selected to avoid any participants with previous lower limb ailments. In addition, increased bodyweight has an understandable association to diabetes onset and foot impediments [23]. Consequently, with both groups classified as overweight fewer gait related pathological conditions are realised. It is the belief of the authors that variables which did reveal statistical significance are of major importance and suggest dissimilar biomechanical patterns exist at the early stage of foot risk included in this study.

Examination of questionnaire responses suggests that the 2 groups were comparable on many levels. Previous research has shown that DM is more prevalent in the male population [2]; 75% of this diabetes group were male. Therefore, the control group also had a weighted gender proportion (p>0.05). The number of DM patients whom were retired was higher than the control group and this most likely reflects the age profile of the participants. Participants did not differ significantly with regard to lifestyle choices such as diet, smoking and alcohol consumption (Table 1). An encouraging point worthy of acknowledgement is that 35% of DM group enrolled had quit smoking and 30% stopped drinking alcohol for a period greater than five years. Thresia et al. [32] reported that but 30 days post diabetes diagnosis, 45% of participants had quit smoking or chewing tobacco but This was not followed up long term. Diet is a major factor for controlling blood sugar levels [33]. Maintenance of blood sugar is important to prevent complications. This cohort indicated good dietary practice with 82.5% of DM group consuming five or more portions of fruit and vegetables a day compared to 57.8% of control group. Physical activity is a factor which is often scrutinized during diabetes research [34]. It has been suggested that a good level of activity is necessary for prevention of foot ulceration [35,36]. DM group for this study indicated a higher level of activity as a means of transport (Table 1). An increased number of the DM group utilized walking and/or cycling to and from places in comparison to control group. Perhaps the patients built exercise into a daily routine, so it was continuous. In contrast, the control group carried out more regimented exercise such as one hour gym work three days a week. The effectiveness of DFU prevention is highly dependent on the adherence of patients to the recommendations set out. This specific DM group heeded advice from

health practitioners, with majority of participants making lifestyle modifications post diagnosis. Perhaps making changes in order to regulate DM maintained participants within the Low-moderate risk category [27].

	DM Patients (n=20)	Control Patients (n=32)	P value ***
Male	15 (75)	26 (81.3)	>0.05
Age (years) *	11 (54.5)	11 (35)	<0.05
Weight (Kg) *	78.5 (60-123)	85 (50-131)	0.6
Height (m) **	172.9 ± 8.5	168.8 ± 10.7	0.13
BMI (Kg/M^2) *	25.5 (19-37.55)	27.73 (23.78-31.13)	0.12
Education (<12 yrs)	10 (50)	14 (43.6)	>0.05
Cohabitation	15 (75)	27 (84.4)	>0.05
Employed	10 (50)	28 (87.5)	>0.05
Currently Smoke	6 (30)	6 (18.75)	0.9
Consume Alcohol	18 (90)	28 (87.5)	>0.05
Alcohol (1-4 days/week)	8 (40)	15 (46.9)	0.755
Fruit & Veg (<5 /day)	16 (82.5)	18 (57.8)	>0.05
Walk/Cycle as transport (4-7 days/week)	12 (60)	10 (30)	-0.12
Sports/Recreation (4-7 days/week)	4 (20)	9 (28.1)	>0.05
Sitting/Relaxing (>4 hours/day)	9 (45)	22 (68.8)	0.73
Hypertension (Clinically Diagnosed)	6 (30)	3 (9.4)	<0.05
Data presented as n (%) unless otherwise indicated			
* Median (Range) ** Mean ± standard Deviation			
*** Chi-square test -categorical variables, t-Test-normally distributed continuous variables, Mann-Whitney Test-non-normally distributed continuous variables			

Table 1: Socio-demographic characteristics.

Foot Care	n (%)
Taught/shown to care for feet	12 (60)
Read educational hand-outs	15 (75)
Never had feet check by health professional	3 (15)
Seen a podiatrist in the last 6 months	4 (20)
Wash feet daily	16 (80)
Dry between Toes	19 (95)
Wash feet daily	7 (35)
Wear shoes at all times	19 (95)
Prescribed Orthotics	5 (25)
Use Orthotics	8 (10)

Table 2: Foot care procedure.

A section on foot care for DM group was included in the questionnaire. The feedback was utilised to assess if the DM group are receiving and heeding information in accordance with guidelines [9,37]. In relation to providing information, there was discrepancy between the proportion of participants whom had received written information and those who attained taught instructions (Table 2). Informative leaflets/ booklets should be given as back up to visually descriptive tutoring. On a positive note, the majority of patients follow the directives they had received and reported to have a successful foot care routine in place. Knowles et al. [38] investigated if people with DM wore their prescribed footwear and detected that Participants wore their shoes 25% of the time. This study showed that 25% of DM group had been prescribed orthotics but only 40% of those prescribed orthotics actually wear them. This demonstrates that patients do not adhere to advice; this can impact on outcomes. This research reports a major increase in plantar pressure and a majority of DM group presented with a weakened/lower arch type. These observations indicate a need for orthotics. Efforts should be made to encourage prescription of orthotics to DM patients whom present with these factors as a preventative intervention. Majority of the reasoning for patients not adhering to use of orthotics are due to ascetics, comfort and lack of education [38-40]. These can be overcome; a correctly made orthotic should fit into regular everyday shoes and should not cause discomfort [41]. It is the opinion of the authors that involving the patient in the assessment process for example describing the

pressure profile of their feet would reiterate the importance of wearing orthotics in accordance with guidelines.

Clinical assessment of foot physiognomies yielded interesting results. A significant association emerged within the DM group between pronation foot alignment and flat arch type. Table 3 highlights 52. 6% of DM group have flat arches, and 42% of DM group fall into the category of pronation. A flat arch is associated with increased bodyweight [26], this could explain the prevalence of this attribute. Interestingly, these groups were matched for BMI and the control group presented with a significantly different frequency of this arch type. This may be due to fact as aforementioned many the DM group have adapted their life to manage their DM and therefore have reduced their BMI. The effects that bodyweight has on foot structure however cannot be reversed. Cavanagh et al. [42] investigated the structural and function characteristics of the foot during walking. It was found that 35% of the variance in plantar pressure was due to foot structure. Therefore, it was concluded by the authors that plantar pressure is in a majority influenced by gait pattern and not the foot structure. A conflicting study reported poor predictability among arch type and foot function stating that low arched feet showed premature loading of the 5th metatarsal area [43]. The results of this study suggest that foot structure has a major impact on plantar pressure. The flat arched patients in this study observed increased and prolonged loading of the M2M3 region. Also, the alignment structure illustrated differences in the loading patterns. The flat arched pronators of the case group displayed elongated loading of the medial metatarsals.

	DM Patients (n=19)	Controls Subjects (n=32)	P value *
Foot Screening			
Pedal Pulses (Present)	18 (94.7)	32 (100)	0.3
Sensation (All Sites Present)	17 (90)	32 (100)	0.26
Arch Type (Flat)	10 (52.6)	5 (15.6)	0.0018
Plantar Flexion (16-30 degrees)	12 (63.2)	16 (50)	0.17
Dorsi Flexion (5- 10 degrees)	11 (57.9)	24 (75)	0.04
Foot Alignment (neutral)	6 (31.6)	17 (53.1)	0.03
Data presented as n (%)			
*Chi-square test -categorical variables			

Table 3: Comparison of Patients Foot Examination Findings.

Patients adapted a self-selected walking speed. In agreement with other studies [17,44] walking speed was significantly less in DM group (Table 4) . Previously this has been reported as a consequent of the onset on neuropathy along with a prolonged double support region; however this collection displayed these parameters prior to neuropathy. The increased time in double support phase is associated with the delayed foot off event, these findings point towards lack of support within the biomechanics of the lower limbs. When discussed in relation to neuropathic patients it is suggested that the differences are due to proprioception deficits, this is something to consider for this low-moderate risk cohort. Studies have previously reported the biomechanical walking properties of DM patients with peripheral neuropathy to be similar to elderly population gait patterns [18,45,46].

	DM Patients (n=20)	Control Patients (n=32)	P value ***
Temporal Parameters			
Cadence (steps/minute) *	112.2 (76.3-126.8)	112.2 (88.7-127.8)	0.4
Stride Time (Seconds) *	1.1 (0.94-1.35)	1.1 (0.85-1.35)	0.5
Step Time (Seconds) *	0.5 (0.47-0.67)	0.5 (0.475-0.685)	0.52
Single Support (Seconds) *	0.4 (0.37-0.54)	0.4 (0.38-0.55)	0.62
Double Support (Seconds) **	0.2 ± 0.03	0.19 ± 0.031	0.024
Foot Off (%) *	0.6 (0.56-0.63)	0.6 (0.49-0.62)	0.002
Stride Length (metres) **	1.2 ± 0.1	1.3 ± 0.1	0.085
Step Length (metres) **	0.6 ± 0.1	0.7 ± 0.1	0.15
Walking Speed (metres/second) **	1.1 ± 0.1	1.2 ± 0.5	0.04

* Median (Range) ** Mean ± standard Deviation
*** Chi-square test -categorical variables, Mann-Whitney Test-non-normally distributed continuous variables

Table 4: Walking Characteristics.

As anticipated, plantar pressure was elevated in the DM group. The metatarsal region and the heel observed significantly increased pressure values compared to the control group. This phenomenon was previously reported in relation to determinants of DFU [7,8, 21,26]. The hallux has been determined as a chief pressure point in patients within a high risk category of ulceration [21,22]. However, this study recorded similar pressures at the hallux in both groups; this was a novel finding. Deformation and reduced ankle flexion are considered causative factors for increased pressure at the hallux [47]. Since patients involved in this study did not present with any of these triggers it is understandable why elevated pressure was not detected here. The increased pressure at the metatarsals and the heel is an important factor. Pressure is amplified at this early stage which would imply that patients are susceptible to callus formation and if not treated effectively may progress to ulceration. Results of this study indicate that foot structure and reduced walking speed greatly increase pressure. This study describes a healthy DM group. However, discrepancies still emerge compared to the control group. It is encouraged following this study, that plantar pressure analysis be included as part of all foot risk categorisation systems, as these danger area would not have been picked up on through a visual examination. The presence of abnormal pressure intensifies the future risk of foot disease to the patient [48].

	DM Patients (n=20)	Controls Subjects (n=32)	P value*
Plantar Pressure (KPa)			
Hallux	340.4 ± 148.5	336.0 ± 164.1	0.926
M2M3	620.3 ± 166.6	479.9 ± 187.0	0.012
Heel	457.5 ± 147.1	363.2 ± 104.0	0.011
Data presented as mean ± St. dev. * t-Test-normally distributed continuous variables. M2M3=Metatarsal 2, Metatarsal 3			

Table 5: Plantar pressure recordings.

Limitations

This study has a number of weaknesses. Patients were compared independent of age. The control group presented a lower mean age (p>0.05). The variables that stood out as dissimilar concerning the temporal parameters were comparable to those previously indicated as linked to an elderly gait pattern [15]. Recruitment of a younger age profile of DM subjects may eliminate these observations. However, it is widely stated that the walking pattern of neuropathic patients share similarities to that of a healthy elderly population [17, 18,44]. No adjustment was made by the authors in the analysis for the confounding factors of age and BMI. Another limiting factor of this study is the small sample size. This paper could be criticised for being underpowered. However, other papers have described similar numbers of participants [49,50]. It would be interesting to see if similar results would be detected in a larger study in the future. A cohort study would be useful to track the progress of a DM group at low-moderate diabetes foot risk and future ulcer development.

Conclusion

The motivation behind this study was to enhance the current literature in relation to the effect of diabetes on the lower limb. It is necessary to tackle the epidemic of diabetes foot disease with preventative pro-active research. Bennet et al. [48] state that identification of high risk patients is the only method for deterrence of foot disease. This study shows that low-moderate risk diabetes patients need and deserve the same care as high risk patients.

The majority of low-moderate foot risk patients in this study displayed differences in ambulation patterns and elevated plantar pressure compared to controls. Thus, the categorisation of foot disease risk of diabetes patients would benefit from the inclusion of an assessment of basic gait parameters and plantar pressure distribution.

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Author Contributions

DOB and MT conceived this study. DOB, CMB, MT, FH and IJP participated in design of study. FH, CMB and MB recruited DM group while DOB and MT recruited control group. DOB, FH and MB carried out participant assessments. DOB, CMB, IJP assisted in drafting the manuscript. All authors read and approved the final manuscript.

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